

REMARKS

The Official Action dated July 14, 2003 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 33, 36, 41, 43 and 64 are amended to correct their dependency or to correct grammatical errors. Claims 44 and 68 are amended to clarify that the plug part is adapted to seal the capsulorhexis without additional sealing means, as set forth in the application, for example, at page 3, lines 15-20. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, the Examiner required an election of species under 35 U.S.C. §121 between Figs. 1A and 1B, Fig. 2 and Fig. 3. Applicants hereby affirm the provisional election of the species of Figs. 1A and 1B. Claims 34-51 and 55-75 read on the elected species. However, the Examiner further withdrew claims 40, 51, 58, 59 and 72 as directed to non-elected species wherein a plug is provided with a cut or a roughened contacting means. The Examiner's withdrawal of these claims is traversed on the basis that claims 40, 51, 58, 59 and 72 do not relate to the species of Figs. 2 or 3 which were the subject of the election of species requirement, and on the basis that the limitations defined by these claims are not mutually exclusive with the embodiment of Figs. 1A and 1B, which mutual exclusivity is required for an election of species. Accordingly, prosecution of claims 40, 51, 58, 59 and 72 on the merits is respectfully requested.

The Examiner objected to informalities in claims 36 and 41 and rejected claim 33 under 35 U.S.C. §112, second paragraph, as depending from a canceled claim. Claim 33 has been amended to depend from claim 68, claim 36 has been amended to recite that the excised

area is of a size sufficient to essentially extend over the visual field, and claim 41 has been amended to recite the amount "of" aberrations, as suggested by the Examiner. It is believed that the objections and the rejection under 35 U.S.C. §112, second paragraph, have been overcome. Reconsideration is respectfully requested.

Claims 33, 44-50, 55-57 and 60-71 were rejected under 35 U.S.C. §102(e) as being anticipated by the Tahi et al U.S. Patent No. 6,358,279. Claims 34-39 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. §103 as unpatentable over Tahi et al. Finally, claims 41-43 and 73-75 were rejected 35 U.S.C. §103 as unpatentable over Tahi et al and further in view of the Werblin U.S. Patent No. 6,413,276. The Examiner asserted that Tahi et al disclose a sealing device 100 adapted to compensate for aberration and comprising a transparent disc-shaped flexible plug 110 made of a deformable silicone polymer and an anteriorly protruding adjusting means 112. The Examiner relied on Werblin as teaching a method of measuring aberrations of the eye and using the data to create a surface to correct for aberrations/abnormalities on the eye or a customized optical element such as an intraocular lens.

However, as set forth in detail below, Applicants submit that the methods defined by claims 33-39, 41-43 and 68-75 and the sealing devices defined by claims 44-50, 55-57 and 60-67 are neither anticipated by nor rendered obvious over Tahi et al, alone or in combination with Werblin. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 44, the present invention is directed to a sealing device for use in ophthalmic surgery to replace a catarcteous and/or presbyopic natural lens, comprising a flexible plug part adapted to seal a capsulorhexis of a capsular bag without additional sealing means and to admit an injection device for injecting a lens-forming liquid material through the capsulorhexis, said plug part having slightly larger area than the

capsulorhexis and being made of a deformable polymer, wherein said sealing device further comprises an anteriorly protruding removable adjusting means connected to the plug part and capable of positioning said plug part to a desired location.

According to claim 34, the invention is further directed to a method of performing visual correction in a patient by replacing the natural lens with a lens implant. The method comprises (a) excising an area of the anterior capsular bag of the eye having a sufficient size to surgically remove the natural lens; (b) locating a sealing device comprising a flexible plug part and removable adjusting means of a size sufficient to cover said excised area with said adjusting means to a position where a peripheral anterior surface of said plug part contacts the inner posterior wall so as to sufficiently cover said excised area; (c) delivering a lens filling material into the capsular bag by using a delivering means to temporarily displace and/or deform said plug part to admit passage into the capsular bag of said material; (d) before removing the delivery means, introducing lens forming material into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of the plug part to seal the excised area, so said lens material is prevented from being displaced from the capsular bag to the posterior chamber of the eye; and (e) finalizing the lens forming process in the eye.

Finally, according to claim 68, the invention is directed to method of obtaining visual correction subsequent to surgically removing the natural lens. The method comprises inserting a plug part of a sealing device through a capsulorhexis, said plug part being adapted to cover and seal the capsulorhexis from the inside of the capsular bag without additional sealing means; adjusting the location of said plug part with an adjusting means operable from the outside of the capsular bag; delivering a lens-forming material through the capsulorhexis into the capsular bag by using a delivering means and by displacing and/or deforming said plug part to admit the material, and removing the delivering means from the eye.

plug part retains a sealing position, thereby preventing displacement of the lens-forming liquid material from the capsular bag.

Advantageously according to the invention, the sealing device and methods employ the plug part which is adapted to seal the capsular bag by the pressure of the lens forming material; therefore, no additional sealing means are required. Particularly, parts protruding from the plug which can damage delicate surrounding eye tissue and/or generate unwanted optical side effects are avoided.

Tahi et al corresponds with WO 00/49976 discussed at page 2 of the present application. Tahi et al disclose a mini capsulorhexis valve device which comprises a curved flexible discoid flap-valve member 110 and a curved flexible retainer member 112 attached at a fastening point to the valve member. In use, the flexible retainer member 112 is situated exterior to the anterior capsule 114 such that the interior capsule wall 116 is disposed between the discoid flap-valve member 110 and the flexible retainer member 112, as shown in Fig. 4d.

Thus, while Tahi et al require the external retainer member 112 to affix and therefore seal the capsulorhexis with the flap-valve member, Applicants find no teaching or suggestion by Tahi et al of a sealing device as recited in claim 44, particularly having a flexible plug part adapted to seal a capsulorhexis of a capsular bag without additional sealing means. Similarly, Applicants find no teaching or suggestion by Tahi et al of a device as recited in claim 45, dependent on claim 44, wherein the sealing device is free from any parts protruding out from the capsular bag subsequent to the surgical process. In fact, the teachings of Tahi et al are inapposite to the devices of claim 44 and 45.

Further, Applicants find no teaching or suggestion by Tahi et al of a method as recited in either claim 34, wherein a lens forming material is introduced into the capsular bag to an extent that said material exerts a sufficient pressure on the posterior side of a flexible plug

part of a sealing device to seal the excised area, or claim 68, wherein a plug part of a sealing device, adapted to cover and seal the capsulorhexis from the inside of the capsular bag without additional sealing means, retains a sealing position, thereby preventing displacement of the lens-forming liquid material from the capsular bag. To the contrary, as noted above, Tahi et al disclose the use of an external retainer member 112.

Finally, Applicants find no teaching or suggestion by Tahi et al of a method or a sealing device employing a plug having optical correction properties, and, particularly, providing reduction of aberrations in a wavefront passing through the sealing device. Thus, the methods and devices of claims 41, 50, 65, 66 and 73-75 are further distinguishable from the teachings of Tahi et al.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of Tahi et al to teach a sealing device as recited in claim 44, or a method as recited in claim 34 or claim 68, Tahi et al do not disclose each and every element as set forth in the claims. Thus, Tahi et al do not anticipate claims 34, 44 or 68, or any of the claims dependent thereon, under 35 U.S.C. §102.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). In view of the deficiencies in the teachings of Tahi et al, and the failure of Tahi et al to teach or suggest modifying their teachings to provide a sealing device including a plug part adapted to seal a capsulorhexis of a capsular bag without additional sealing means, or methods employing sealing devices as defined in claims 34 and 68, Tahi et al do not enable one of ordinary skill in the art to make the sealing device of claim

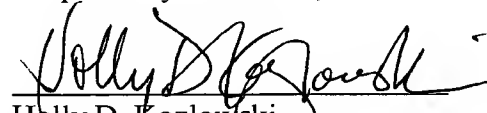
44 or to use the methods of claims 34 and 68. Thus, Tahi et al do not render claims 34, 44 and 68, or any of the claims dependent thereon, obvious under 35 U.S.C. §103.

Finally, the deficiencies of Tahi et al are not resolved by Werblin. That is, Werblin is directed to a method of correcting optical aberrations and abnormalities with an optical system having an intraocular lens implant. Applicants find no teaching or suggestion by Werblin relating to correcting an aberration by use of a sealing device, or for modifying the teachings of Tahi et al along the lines of the present invention.

Accordingly, the methods defined by claims 33-39, 41-43 and 68-75 and the sealing devices defined by claims 44-50, 55-57 and 60-67 are neither anticipated by nor rendered obvious over Tahi et al, alone or in combination with Werblin, whereby the rejections under 35 U.S.C. §§102 and 103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102, 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Holly D. Kozlowski
Registration No. 30,468
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568